

PROPOSAL

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Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 05 FREESTANDING AMBULATORY CARE FACILITIES

Notice of Proposed Action

[15-399-P]

The Secretary of Health and Mental Hygiene proposes to amend:

- (1) Regulation .05 under **COMAR 10.05.01 General Requirements**; and
- (2) Regulation .01 under **COMAR 10.05.05 Freestanding Ambulatory Surgical Facilities**.

Statement of Purpose

The purpose of this action is to amend the definitions for “freestanding ambulatory surgical facility” and “surgical services” to be consistent with the statutory amendments to these definitions. Also, in accordance with statutory amendment, the proposal requires the Department to survey freestanding ambulatory care facilities in accordance with federal regulations.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through January 27, 2016. A public hearing has not been scheduled.

10.05.01 General Requirements

Authority: Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland

.05 Inspections by Secretary of Health and Mental Hygiene.

A. Open for Inspection. A licensed facility or an entity proposing to operate such a facility shall be open during normal business hours, or any other times that the facility is serving patients, for inspection by the Department and by any other agency designated by the Department to:

(1) *Survey freestanding ambulatory care facilities as directed by the Centers for Medicare and Medicaid Services;*

[(1)] (2) Verify compliance with licensing regulations; [and] *or*

[(2)] (3) Investigate complaints.

B.—C. (text unchanged)

10.05.05 Freestanding Ambulatory Surgical Facilities

Authority: Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) (text unchanged)

(2) Freestanding Ambulatory Surgical Facility.

(a) "Freestanding ambulatory surgical facility" means a facility, service, office facility, or other entity that:

(i) Operates [primarily] *exclusively* for the purpose of providing surgical services to patients requiring a period of postoperative observation but not requiring [overnight] hospitalization *and in which the expected duration of services would not exceed 24 hours following admission*; and

(ii) (text unchanged)

(b) (text unchanged)

(3)—(4) (text unchanged)

(5) *Surgery*.

(a) "*Surgery*" means a procedure conducted for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine.

(b) "*Surgery*" includes:

(i) *The diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include, lasers, ultrasound, ionizing radiation, scalpels, probes, and needles;*

(ii) *Cut, burned, vaporized, frozen, sutured, probed, or manipulated tissue by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means; or*

(iii) *Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system.*

[(5)] (6) "Surgical services" means [an invasive procedure whether therapeutic or diagnostic involving the use of:

(a) Any cutting instrument;

(b) Microscopic, endoscopic, arthroscopic, or laparoscopic equipment; or

(c) Laser for the removal or repair of an organ or other tissue.] *surgical procedures performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ambulatory surgical center in accordance with approved policies and procedures of the ambulatory surgical center.*

VAN T. MITCHELL

Secretary of Health and Mental Hygiene